

CLAIM AMENDMENTS

1-19. (canceled)

20. (currently amended): A vial containing a [[dry]] dried native Factor VIII composition comprising a Factor VIII-stabilizing amount of trehalose and no albumin, the composition being

- (a) stable without refrigeration, and
- (b) suitable for reconstitution with water or with an aqueous solution for administration to a hemophilic patient by injection.

21. (previously presented): The composition of claim 20, containing 0.15 to 2.5 mg trehalose per unit of Factor VIII.

22. (previously presented): The composition of claim 20, wherein said native Factor VIII is recombinant.

23. (previously presented): The composition of claim 20, containing 1.0 to 1.5 mg Ca²⁺ per unit of Factor VIII.

24. (previously presented): The composition of claim 20, wherein the composition comprises salt and the molar ratio of trehalose to the salt is above 1:1.

25. (previously presented): The composition of claim 24, containing more than 2.5 moles trehalose per mole of salt.

26. (previously presented): The composition of claim 25, containing more than 10 moles trehalose per mole of salt.

27. (currently amended): A process ~~of preparing a dry~~ ~~for preparing the dried native Factor VIII composition defined in claim 20 which comprising a Factor VIII stabilizing amount of trehalose and no albumin, the composition being~~

(a) ~~stable without refrigeration, and~~

(b) ~~suitable for reconstitution with water or with an aqueous solution for administration to a hemophilic patient,~~

~~the process comprising comprises~~ drying a solution of native Factor VIII and trehalose in the absence of albumin.

28. (previously presented): The process of claim 27, wherein the drying is done at a temperature of no greater than 10°C.

29. (previously presented): The process of claim 28, wherein the drying is freeze-drying.

30. (previously presented): The process of claim 27, wherein an aliquot of the solution is placed in a vial and is freeze-dried.

31. (currently amended): ~~[[The]] A~~ method for preparing a Factor VIII therapeutic composition for administration to a patient wherein the method comprises reconstituting the composition ~~[[ef]] defined in~~ claim 20 to obtain a solution that is suitable for injection.

32. (previously presented): The method of claim 31, wherein the reconstituting is with water.

33. (previously presented): The method of claim 31, wherein the reconstituting is with saline.